# THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 19

# UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte HUM M.L. DAVIES, STEVEN R. CHILDERS and BARBARA BENNETT

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Appeal No. 95-3746Application 08/063,431<sup>1</sup>

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HEARD: February 12, 1999

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Before KIMLIN, OWENS, and SPIEGEL, Administrative Patent Judges.

OWENS, Administrative Patent Judge.

# DECISION ON APPEAL

This is an appeal from the examiner's final rejection of

<sup>&</sup>lt;sup>1</sup> Application for patent filed May 18, 1993. According to the appellants the application is a continuation-in-part of Application 07/851,090, filed March 13, 1992, now Patent 5,262,428, issued November 16, 1993.

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claims 1-16, which are all of the claims in the application.

# THE INVENTION

Appellants claim methods for treating mammals to selectively block the uptake of serotonin (5-HT) and dopamine by administering to the mammals tropane derivatives having a

recited formula.

Claim 1 is

illustrative and

reads as follows:

A method mammals to
 HT uptake, said

 $R_4 N \frac{R_2}{12} R_3 R_3$ 

of treating selectively block method comprising:

administering a small but effective amount of a 3-aryltropane derivative of the formula:

and structural isomers thereof,

wherein  $R_1$  is an aromatic ring moiety selected from the group consisting of 1-naphthyl, 1-naphthyl, phenyl,  $C_1$  to  $C_8$  alkylaryl, and indole; and

 $\rm R_2$  and  $\rm R_3$  may be the same or different and are selected from the group consisting of hydrogen,  $\rm C_1$  to  $\rm C_8$  ketones, and

 $R_4$  is methyl, hydrogen or lower alkyl.

#### THE REJECTIONS

Claims 1-16 stand rejected under 35 U.S.C. § 101 on the ground that the claimed invention lacks patentable utility, and under 35 U.S.C. § 112, first paragraph, on the ground that the specification fails to provide an enabling disclosure.

# OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejection is not well founded. Accordingly, we do not sustain this rejection.

Rejection under 35 U.S.C. § 101

Before utility is determined, the claims must be interpreted to define the invention to be tested for utility. See Raytheon Co. v. Roper Corp., 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), cert denied, 469 U.S. 835 (1984). "Claim construction is a question of law, reviewed non-deferentially on appeal." Mantech Environmental Corp. v. Hudson Environmental Services, 152 F.3d 1368, 1371, 47 USPQ2d 1732, 1735 (Fed. Cir. 1998).

Appellants claim methods for treating mammals to

selectively block the uptake of serotonin (5-HT) (claims 1-8 and 12-16) or dopamine (claims 9-11). The examiner's interpretation (answer, page 4) of the claims as being methods for treating the diseases disclosed in appellants' specification, such as Parkinson's disease, clearly is incorrect.

Appellants provide in vitro data in their specification (Table 1, page 22) which show that the claimed methods are useful for selectively blocking the uptake of serotonin and dopamine. The examiner argues that such methods are devoid of utility absent a showing that they are inexorably linked to the treatment of a particular disease (answer, pages 7-8). This argument is not well taken because the selective blocking of the uptake of serotonin and dopamine are pharmacological activities, and in the pharmaceutical arts, "practical utility may be shown by adequate evidence of any pharmacological activity." Fujikawa v. Wattanasin, 93 F.3d 1559, 1564, 39 USPQ2d 1895, 1899 (Fed. Cir. 1996).

The examiner argues that appellants have not shown that their in vitro tests indicate in vivo activity (answer, page

- 8). A predecessor of our appellate reviewing court stated in In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974):
  - [A] specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Each case of practical utility must be decided on its own facts. See Fujikawa v. Wattanasin, 93 F.3d at 1564, 39 USPQ2d at 1899. The examiner has not carried her initial burden of providing evidence or sound technical reasoning which indicates that one of ordinary skill in the art would have questioned the objective truth of appellants' supported statements in their specification that their claimed methods are useful for treating mammals to selectively block the uptake of serotonin or dopamine.

For the above reasons, we do not sustain the rejection under 35 U.S.C.  $\S$  101.

Rejection under 35 U.S.C. § 112, first paragraph
Regarding enablement, a predecessor of our appellate

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reviewing court stated in *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369-70 (CCPA 1971):

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. . . .

. . . .

. . . it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

The examiner argues that there is insufficient enablement in appellants' specification for one of ordinary skill in the art to treat the various conditions suggested in appellants' specification (answer, page 5). This argument is not relevant because, as discussed above, appellants claim methods for selectively blocking the uptake of serotonin or dopamine, not methods for treating Parkinson's disease or other diseases

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mentioned in their specification. The examiner has not carried her initial burden of providing evidence or sound technical reasoning which indicates that appellants' specification would not have enabled one of ordinary skill in the art to carry out the claimed methods for treating mammals to selectively block the uptake of serotonin or dopamine.

Consequently, we do not sustain the rejection under 35 U.S.C. § 112, first paragraph.

#### DECISION

The rejections of claims 1-16 under 35 U.S.C. § 101 on the ground that the claimed invention lacks patentable utility, and under 35 U.S.C. § 112, first paragraph, on the ground that the specification fails to provide an enabling disclosure, are reversed.

# REVERSED

EDWARD C. KIMLIN	)			
Administrative Patent Judge	)			
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	)			
	)	BOARD	OF	PATENT
TERRY J. OWENS		)		

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